REMARKS

Claim Amendments

Claims 1, 13, 16, and 18 have been amended and claim 41 has been added. No claims have been deleted. No new matter has been added. Upon entry of the above amendments, claims 1-7, 9-13, 16-22, 24-25, and 41 will be pending. However, Applicant submits that claims 8, 23, and 26-40 should be added back in upon an indication of allowable subject matter in generic claim 1 or 18.

Claim Rejections - 35 USC § 112

Claims 16, 18-22 and 24-25 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the claim(s) allegedly contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 16 and 18 have been amended to obviate this rejection by deleting references to "foot" stimulation and instead claiming "muscle" stimulation in a manner consistent with the examiner's comments. Withdrawal of the rejection of claims 16, 18-22, and 24-25 under 35 U.S.C. 112, first paragraph, is solicited.

Claim Rejections - 35 USC § 103

Claims 1-6, 9-12, and 16-17

Claims 1, 3 10 and 16 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable as obvious over Havriluk (US Pat 5,005,140). Claims 1-3, 11, 12 and 16 also stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable as obvious over Hochberg (US Pat 4,989,615). Claims 4, 5, and 9 also stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable as obvious over Havriluk in view of Toms (US Pat 6,036,660). Claim 6 stands rejected under 35 U.S.C. 103(a) as allegedly being unpatentable as obvious over Havriluk and Toms further in view of McEwen et al. (US PG Pub 2003/0036771 A1). Finally, claims 1 and 17 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable as obvious over Havriluk in view of Goldman (US Pat 5,775,332). These rejections are respectfully traversed.

Claim 1 has been amended to obviate these rejections. In particular, claim 1 has been amended to recite "a control unit that receives the electrical output signals as input signals and provides feedback to affect movement at said location, said control unit being part of one of a weight bearing biofeedback system and an electrical stimulation system." A force sensor system with such characteristics is nowhere shown or suggested by the cited prior art.

The examiner alleges with respect to claim 1 that Havriluk discloses a force sensor system for monitoring weight bearing at a location on a person comprising each of the claimed elements. The examiner further alleges that it would have been obvious to one of ordinary skill in the art at the time the invention was made "that the electrical output signals would be indicative of weight bearing on the location since the device is designed for a patient to place weight on the pockets. Applicant disagrees.

Havriluk teaches measuring pressure changes in fluids and using the measured values to calculate "exercise peak force, average force" (col. 5, lines 28-44) and an "area under the curve" (col. 1, lines 8-10). However, Havriluk does not teach measuring the weight force as Havriluk does not teach a conversion of the measured pressures into pounds. Applicant notes that this process is not as straightforward as the examiner might imply. Conversion or "calibration" of the force foot insole is a challenge mainly because there is not a linear relationship across the entire weight range between sensor readings and the actual pressures (forces) applied to the insole. For a desired range of 0 – 250 pounds, a linear relationship has been found to exist between sensor output and weight for mid-range values only. This is because, in part, the pressure in the system is not simply the foot force divided by the insole area, but is a complex interaction between the foot, the insole, and the shoe, and it depends on factors such as the elasticity of the foot's soft tissue and the pneumatic compliance of the air cells. The resulting foot force – output pressure relation is a non-linear function that requires calibration with a look-up table that is built up differently in static measurements and dynamic measurements with a human foot on a force plate to address the resultant non-linearities.

Also, in Havriluk, data is collected, analyzed and displayed (*e.g.*, "Pressure vs time" at col. 5, lines 29-31). Havriluk does not teach or suggest biofeedback or electrical stimulation to, for example, correct/guide weight bearing or heel to toe placement or to enhance weight bearing

on the entire foot, hind foot or forefoot. In particular, in Havriluk's system the electrical input signal is just a pressure level and is not in any way related to an electrical stimulation to affect movement or to any kind of biofeedback as claimed. Contrary to the examiner's allegations, Havriluk simply provides information, data, and results. Havriluk provides no feedback based on such information, data, or results and thus does not suggest the features of claim 1. Moreover, Havriluk certainly provides no teaching of providing feedback based on weight bearing throughout the person's gait based on a gait analysis to provide input signals that "identify specific stages of a gait cycle of the foot" and provides no teaching of an electrical stimulation system that "uses the input signals to activate an electronic orthosis" as recited in claim 17. Havriluk also does not convert the measured pressure signals to weight in pounds in order to provide the claimed feedback. Absent such teachings, Havriluk could not have suggested the force sensor system of amended claim 1 to one skilled in the art. Withdrawal of the rejection of claim 1 over Havriluk is solicited.

The examiner further alleges with respect to claim 1 that Hochberg discloses a force sensor system for use in monitoring weight bearing at a location on a person, comprising each of the claimed elements. The examiner further alleges that it would have been obvious to one of ordinary skill in the art at the time the invention was made "to modify Hochberg so that a biofeedback system indicative of some type of weight bearing were provided for the patient since pressure sensors are already disposed to detect the pressure applied to at least one pocket and providing this feedback would be beneficial and educational for the patient." Applicant respectfully disagrees.

Like Havriluk, in Hochberg's system the electrical input signal is just a pressure level that is not in any way related to an electrical stimulation to affect movement or to any kind of biofeedback as claimed. Contrary to the examiner's allegations, Hochberg provides no feedback based on the collected information, data, or results and thus does not suggest the features of claim 1. Moreover, Hochberg provides no teaching of providing feedback based on weight bearing throughout the person's gait based on a gait analysis to provide input signals that "identify specific stages of a gait cycle of the foot" and provides no teaching of an electrical stimulation system that "uses the input signals to activate an electronic orthosis" as recited in

claim 17. The pressure monitor at the fetal monitor of Hochberg cannot be indicative of weight bearing without a conversion process of pressure into pounds. However, such considerations are not relevant to the system of Hochberg, and, in any case, Hochberg does not convert the measured pressure signals to weight in pounds in order to provide the claimed feedback. Absent such teachings, Hochberg could not and would not measure weight bearing and provide feedback as claimed. Accordingly, Hochberg could not have suggested the force sensor system of amended claim 1 to one skilled in the art. Withdrawal of the rejection of claim 1 over Hochberg is solicited.

New claim 41 further emphasizes the distinctions between the claimed force feedback system and Havriluk and Hochberg by specifying that the claimed feedback includes "audio, visual and/or mechanical vibration feedback that prompts a patient to shift the balance of weight on the location and/or to adjust the patient's gait or standing posture." Such a force feedback system is in no way shown or suggested by Havriluk or Hochberg. As a result, neither Havriluk nor Hochberg teach or suggest the claimed benefits of the claimed force sensor system whereby the audio and visual feedback permits load target learning, intended to increase or limit weight bearing, and gait pattern learning, intended to train the patient in the correct kinematics and load bearing transfer. The biofeedback training made possible by the claimed force sensor system enhances the relearning of all aspects of lower limb motor function, including standing up, walking, stair climbing and balance and proprioceptions - weight distribution and sensation of weight distribution and movement of weight between hind foot and forefoot during standing and weight shifting. The systems taught by Havriluk and Hochberg do not provide such feedback and thus do not enable such significant benefits. Withdrawal of the rejections of claim 1 over Havriluk or Hochberg is solicited.

Toms is cited for the particulars of a flexible pouch as claimed in claims 4, 5, and 9 and has no teachings relevant to the above-mentioned shortcomings in the teachings of Havriluk or Hochberg. Similarly, McEwen is cited for teaching particulars of the fabric sheets of the flexible pouch as claimed in claim 6 and has no teachings relevant to the above-mentioned shortcomings in the teachings of Havriluk or Hochberg. Accordingly, even if the teachings of Toms and/or McEwen could have been used to modify the teachings of Havriluk as the examiner suggests, the

force sensor system of claim 1 would not have resulted. For at least these reasons, independent claim 1 and dependent claims 2-6, 9-12, and 16 are believed to be nonobvious over the collective teachings of Havriluk, Toms, and McEwen. Withdrawal of the rejections of these claims is solicited.

With respect to claims 1 and 17, the examiner further cited Goldman as allegedly teaching a weight sensing device with an associated electronic module that provides electrical stimulation. From the teachings of Goldman, the examiner alleged that it would have been obvious to one of ordinary skill in the art at the time the invention was made to "modify Havriluk to include the electrical stimulation system as taught by Goldman in order to provide feedback to the patient about the amount of weight bearing occurring, and to help the patient maintain safe weight bearing." Again, Applicant disagrees.

Goldman teaches combining an electronic sensory cueing to the heel with a plastic AFO (Ankle foot orthoses). However, contrary to the examiner's allegations, Goldman does not teach electrical stimulation of the muscles as an alternative for an AFO. As with Havriluk, Goldman does not provide feedback to affect movement at a measurement location as in claim 1 and does not "identify specific stages of a gait cycle of the foot" whereby "the electrical stimulation system uses the input signals to activate an electronic orthosis" as recited in claim 17. Goldman is instead concerned with using biofeedback to limit weight balancing and provides no teachings that would enable one to enhance weight bearing on the entire foot, train a gait pattern by enhancing loading on hind-foot or forefoot or both), train balance and proprioception (sensation of movement) by working on weight distribution between hind-foot and forefoot during standing and weight shifting by providing feedback to "affect movement" as claimed. For example, the claimed force sensor system may use electrical stimulation with an electrical orthoses that activates the muscles to get a correct heel strike or dorsi flexion during the swing phase of the patient's gait. Accordingly, even if one skilled in the art would have combined the teachings of Goldman with Havriluk as the examiner suggests, the force sensor system of claims 1 and 17 would not have resulted. Withdrawal of the rejections of claims 1 and 17 is solicited.

Claim 13

Claim 13 stands rejected under 35 U.S.C. 103(a) as allegedly being unpatentable as obvious over Havriluk in view of Rechin et al. (US Pat 6,145,142). Claim 13 has been amended to depend from claim 1 and is believed to be allowable for the same reasons as noted above with respect to claim 1 by virtue of its dependency upon claim 1. Applicant further notes that nothing in the teachings of Rechin is believed to be relevant to the above-mentioned shortcomings in the teachings of Havriluk or Hochberg. Withdrawal of the rejection of claim 13 is solicited.

Claims 18, 20-22, and 24-25

Claims 18 and 20-22 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable as obvious over Havriluk in view of Goldman. Also, claim 19 stands rejected under 35 U.S.C. 103(a) as allegedly being unpatentable as obvious over Havriluk in view of Goldman and Hochberg, while claims 24 and 25 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable as obvious over Havriluk in view of Goldman and Vredenbregt et al. (US Pat 3,881,496). In addition, claim 18 stands rejected under 35 U.S.C. 103(a) as allegedly being unpatentable as obvious over Havriluk in view of Rosenberg (US Pat 4,610,253). These rejections are respectfully traversed.

In rejecting claim 18, the examiner alleges that Havriluk discloses a foot stimulation system for use in control of an electronic orthosis as claimed. The examiner acknowledges that Havriluk does not disclose the claimed stimulator that delivers stimulation to a foot in response to the electrical output signals and a controller that receives the electrical output signals from the pressure sensors as input signals to activate the stimulator to deliver stimulation to a first muscle group in response to input signals from the heel pressure sensor and activating the stimulator to deliver stimulation to a second muscle group in response to input signals from the forefoot pressure sensor as claimed. However, the examiner alleges that Goldman teaches a stimulator that delivers stimulation to a foot and further alleges that Goldman teaches stimulation in response to specific types of weight bearing. From such teachings, the examiner alleged that it would have been obvious to one of ordinary skill in the art at the time the invention was made to "modify Havriluk to include the stimulator as taught by Goldman in order to provide feedback to the patient about the amount of weight bearing occurring, and to help the patient maintain safe weight bearing … [and] to include a controller for the activation of the stimulator capable of

delivering stimulation to different muscle groups in response to different types of weight bearing as taught by Goldman in order to provide detailed feedback to the patient about the type of weight bearing occurring." As noted above with respect to claims 1 and 17, Havriluk and Goldman together do not teach or suggest the claimed feedback stimulation.

As noted above, Havriluk does not disclose foot stimulation and does not provide feedback for such purposes. Moreover, Havriluk does not measure forces as claimed. In particular, Applicant notes that while Havriluk mentions peak force, Havriluk does not teach conversion from pressure to body weight on a foot in order to provide the claimed feedback. Goldman does not provide the claimed electrical stimulation either. Instead, Goldman mentions a sensory cue for the heel when used with ankle foot orthoses to reinforce the sensation of heel contact. As noted above, Hochberg does not provide the claimed electrical stimulation feedback. Applicant submits that electrical stimulation feedback is not taught by Vredenbregt or Rosenberg either. Such teachings, even if combined, fall far short of suggesting the foot stimulation system of claim 18. For at least these reasons, withdrawal of the rejection of claim 18 over Havriluk and Goldman is appropriate.

Finally, in rejecting claim 18 over Havriluk in view of Rosenberg, the examiner acknowledged that Havriluk does not disclose a stimulator that delivers stimulation to an area around the foot in response to the electrical output signals; however, the examiner further alleges that Rosenberg teaches a device that "senses weight bearing applied to pressure sensors 2 and a stimulator ... that delivers stimulation in response to electrical signals converted from the pressure signals." From such teachings, the examiner alleges that it would have been obvious to one of ordinary skill in the art at the time the invention was made to "modify Havriluk to incorporate an electrical stimulator as taught by Rosenberg in order to provide a more noticeable indication of weight bearing by the patient. Again, applicant disagrees.

Rosenberg uses an electrical indicator, a vibrator, a visual alarm or an audio alarm as a feedback to the patient that a discomfort area of the foot is loaded and that he needs to shift weight from this part of the foot to prevent a pressure sore. Rosenberg does not teach using electrical stimulation to stimulate a muscle group as claimed in claim 18. Accordingly, even if the teachings of Rosenberg could have been combined with the teachings of Havriluk as the

examiner suggests, the claimed foot stimulation system would not have resulted. Withdrawal of the rejection of claim 18 over Havriluk and Rosenberg is respectfully solicited.

For at least these reasons, claims 18-22 and 24-25 are allowable over any proposed combination of the teachings of Havriluk, Goldman, Hochberg, Vredenbregt, or Rosenberg. Allowance of claims 18-22 and 24-25 is solicited.

Allowable Subject Matter

Applicant appreciates the examiner' allowance of claim 7. The remaining claims are believed to be allowable for the reasons noted above.

Conclusions

The cited prior art fails to teach or suggest a force feedback system or a stimulation system that provides feedback to affect movement such as providing electrical muscle stimulation based on measured pressures from pressure sensors as claimed in claims 1-7, 9-13, 16-22, 24-25, and 41. A Notice of Allowability is solicited.

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